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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,094	10/22/2004	Abdurrahman Mithat Bozdayi	BJS-2551-158	4496

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EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,094	BOZDAYI, ABDURRAHMAN MITHAT	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 38-40* is/are pending in the application.

4a) Of the above claim(s) *31-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-30 and 38-40* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Withdrawn Rejections

The rejection of claims 13-20 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,422,848 has been withdrawn in view of the Terminal Disclaimer filed by applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6, 8-30 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to, *inter alia*, an isolated HBV polynucleic acid comprising a reverse transcriptase encoding domain, said reverse transcriptase encoding domain comprising a serine encoding codon at position 204.

There is insufficient description of the structure or function of the polynucleic acid to convey to one of ordinary skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The applicable standard for the written description requirement can be found in MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004). To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only identifying factor present in the claims is a serine encoding codon at position 204. However, because there is no reference sequence provided and because the open language “comprising” is used to describe the HBV polynucleic acid length, one of ordinary skill in the art would not know where position 204 is located. The claims encompass a large genus of polynucleotides of varying sizes, and counting from the first codon of these sequences will give a different result for position 204.

The court clearly states in Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to

recognize that the inventors invented what is claimed. As discussed above, the skilled artisan cannot envision the detailed chemical structure of the claimed genus.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-6, 8-30 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Because there is no reference sequence provided and because the open language "comprising" is used to describe the HBV polynucleic acid length, one of ordinary skill in the art would not know where position 204 is located. The claims encompass a large genus of polynucleotides of varying sizes, and counting from the first codon of these sequences will give a different result for position 204. Accordingly, one of ordinary skill in the art cannot determine the metes and bounds of the claims.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 refers to position 204 of the HBV protein and claim 7, which depends from claim 4, references SEQ ID NO:4. It is unclear how SEQ ID NO:4 can have a position 204 when it only has 160 amino acids.

Claims 13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims are directed to methods for detecting the presence of HBV and for detecting HBV resistance to lamivudine. However, there are no steps present in either claim for carrying out the claimed method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (Hepatology, 1998;27:1670-1677).

The claims are directed to methods for detecting HBV by obtaining an HBV polynucleic acid suspected of having certain mutations, sequences the polynucleic acid and inferring from the results the presence of HBV in the sample.

It is noted that the claim is being interpreted as comprising two steps: i) obtaining an HBV polynucleic acid, and (ii) sequences the polynucleic acid. The phrase

"suspected to comprise a serine-encoding codon at position 204 . . . ." has no meaning in the claim because it is not known, at the time of performing the method, whether or not the HBV DNA has any mutations. Further, the inferring step or clause does not recite any additional active method steps, but simply states a characterization or conclusion of the previous step(s) or may be performed entirely in the human mind. Therefore, the "inferring " step or clause is not found to further limit the method defined by the claims, since it simply expresses the intended result of a positively recited process step.

Allen et al. teaches sequencing HBV DNA using primers that fall within the HBV polymerase gene. Thus, Allen et al. anticipates claims 14 and 18

Claims 21, 22, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Zaaijer et al. (J Clin Microbiol, 1994, 32(9):2088-2091).

It is noted for claims 21 and 25, the claims are interpreted as being directed to a kit for detecting the presence of HBV reverse transcriptase polynucleic acid. It is also noted for claims 22 and 26 that step (i) is optional. Thus, for purposes of this rejection, claims 22 and 26 are interpreted as not including the optional step (i) and only further including a means for inferring the presence of HBV in the sample.

Zaaijer et al. discusses and compares four commercial kits used to detect HBV DNA. The kits use PCR or hybridization to detect HBV DNA from HBsAg and HBeAg (polymerase/reverse transcriptase). These kits, especially the hybridization kits, are sufficient to detect HBV nucleic acid with a single mutation at codon 204. As for claims

22 and 26, these kits contain a means (e.g., a hybridization probe) for inferring the presence of HBV in the sample.

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648